"Dedicated to the Health
of the Whole Community"

AMBULATORY & COMMUNITY
HEALTH SERVICES

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PACE/AIDS Medicine Referral Guidelines

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This information is designed to aid practitioners in making decisions about appropriate medical care. These guidelines should not be construed as dictating an exclusive course of treatment. Variations in practice may be warranted based on the needs of the individual patient, resources, and limitations unique to the institutional type of practice.

E-CONSULT DISCLAIMER:
E-consults are based on the clinical data available to the reviewing provider and are furnished without benefit of a comprehensive evaluation or physical examination. All advice and recommendations must be interpreted in light of any clinical issues, or changes in patient status, not available to the reviewing provider. The ongoing management of clinical problems addressed by the e-consult is the responsibility of the referring provider. If you have further questions or would like clarifications regarding e-consult advice, please contact the reviewing provider. If needed, the patient will be scheduled for an in-office consultation.

All URGENT consultations require provider-to-provider communication, please page MD on call for PACE for any URGENT referrals. If your patient has a medical emergency, please direct them to the closest emergency room for expedited care.

Please note: ALL patients referred to the PACE clinic must have confirmatory HIV testing and have HIV positive results shared by the PCP PRIOR to referral.

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HIV

1. **Background**
    a. Diagnosis codes
        i. ICD-10 codes: B20 (preferred), Z21
    b. **Symptoms concerning for acute HIV which would entail HIV RNA quant test**: fever, fatigue, myalgia, rash, pharyngitis, cervical adenopathy, arthralgia, night sweats, diarrhea

2. **Pre-referral evaluation and treatment**
    a. REQUIRED Testing - BEFORE referral
        i. HIV-1 and HIV-2 antibodies
        ii. Confirmatory test
            1. 4th generation HIV Ab/Ag test and Geenius confirmation test at VMC (lab automatically runs confirmatory test for positive screen)
            2. Or possibly 3rd generation Ab test followed by Western blot or HIV RNA at other labs
        iii. **Please discuss diagnosis of HIV with patient before referral.** Our schedulers are not trained to disclose HIV test results. If PCP needs counseling on how best to disclose diagnosis to patient, please page PACE on call physician to discuss. We presume at time of referral placement to PACE that the patient has already been informed of the diagnosis.
    b. ADDITIONAL Testing - helpful prior to referral to PACE if possible (optional)
        i. CBC with diff, T cell subset (CD4) basic metabolic panel (P7), phosphorus, LFTs, HIV-1 RNA quant PCR (viral load), HIV-1 genotype, HLA-B*5701, toxoplasma gondii antibody IgG, Anti-HAV IgG, Hepatitis B surface antigen, Hepatitis B surface antibody, Hepatitis C antibody (or hepatitis C RNA quant PCR if known diagnosis of hepatitis C), Vitamin D for Nutritional Status, Syphilis, urine gonorrhoeae and chlamydia amplification, oral and rectal GC amplification (if patient engages in oral/anal sex), urinalysis, lipid panel, G6PD, QuantiFERON
    c. Previously diagnosed patients lost to follow up or transferring care to VMC:
        i. CBC with diff, T cell subset (CD4), basic metabolic panel (P7), LFTs, HIV-1 RNA quant PCR (viral load)

3. **Indications for referral**
    a. HIV positive patients

4. **Please include the following with your referral**
    a. Results of pre-referral testing, as indicated
    b. For transfers from another institution, please obtain medical records from prior clinic and scan records to Healthlink or attach to initial PACE referral.

HIV PRE-EXPOSURE PROPHYLAXIS (PrEP)

1. **Background**
    a. ICD-10 Diagnosis codes
        i. Contact with or exposure to viral disease- Z20.828
        ii. High risk sexual behavior- Z72.51
        iii. HIV counseling- Z71.7
    b. What is PrEP?
        i. FDA approved emtricitabine/tenofovir (FTC/TDF, or Truvada) to reduce risk of sexually acquired HIV infection in adults with elevated risk. It is taken daily regardless of plans for sex. It requires regular monitoring for HIV infection, STDs, drug safety and adherence. PrEP is highly efficacious for those who take it consistently, but adherence is a major factor.
        ii. PrEP should not be offered as sole intervention for HIV prevention. PrEP should only be prescribed as part of a comprehensive prevention plan with safe sex counseling and STD screening. Although consistent condom use is a critical part of a prevention plan, lack of use of barrier protection is not a contraindication to PrEP.
    c. Who is PrEP appropriate for?
        i. Men who have sex with men (MSM) who engage in condomless receptive anal intercourse
        ii. MSM with multiple anal sex partners
        iii. MSM with syphilis or rectal STDs
        iv. MSM with one or more HIV-positive sex partners (particularly if partner is not in care or does not have undetectable viral load)
        v. Heterosexual men and women with one or more HIV-positive partners
        vi. Injection drug users
        vii. Patients with high risk sexual practices who have needed post-exposure prophylaxis more than twice
        viii. **AND GFR>60 without acute HIV**

2. **Pre-referral evaluation and treatment-** PrEP candidates should be referred for evaluation, initiation and follow up of PrEP by staff of the PACE clinic by placing a referral in health link the MPC PREP department or by calling the PACE clinic at 408 885 4690.

If initiating PrEP:

a. Baseline labs that should be obtained prior to starting PrEP
    i. HIV antibody test (must test negative within 1 week prior to starting PrEP), HIV RNA quant (if any risky exposure within last 2 weeks or symptoms concerning for acute HIV infection), STD screening (syphilis, gonorrhea, chlamydia), kidney function test (Cr), hepatitis B surface antigen and hepatitis B core antibody
        1. **MOST IMPORTANTLY** PrEP should only be started after HIV is ruled out. Prescription for PrEP should be delayed until confirmation of a negative test result.

b. Management
    i. PrEP patients require frequent STD counseling and testing with their primary care physician. PACE physician on call is available by phone, pager, email to discuss questions/side effects that may come up while on treatment.
    ii. **Patients with known hepatitis B or who test positive for hepatitis B on screening:**
        1. Both emtricitabine and tenofovir are also active against hepatitis B so any patient who is found to have hepatitis B should be co-managed with GI clinic because discontinuation of PrEP at any time can result in a hepatitis B flare. Please have GI clinic evaluate patient BEFORE initiating PrEP to determine if concomitant treatment of hepatitis B is reasonable. If a hepatitis B positive patient is not ready to commit to treatment of their hepatitis B, PrEP should not be given.
    iii. PrEP prescription:
        1. Initial prescription for emtricitabine/tenofovir (FTC/TDF, or Truvada 1 tablet daily) should only be for 30 days.
            a. Follow up visit should be done within 2-4 weeks to assess adherence, tolerance, commitment and retest for HIV to rule out seroconversion.
            b. At second visit, 90-day prescriptions can be given and patients MUST return once every 90 days for testing and counseling.
        2. Insurance coverage
            a. Insured patients

i. Medi-Cal no longer requires prior authorization for PrEP as of 4/2014
ii. Most private insurance plans including VHP cover PrEP without prior authorization
iii. If high co-pay or uninsured please contact PACE clinic at 408 885 4690 for consultation and advice

3. **Follow up labs**
    a. Patient should be screened every 3 months for HIV and for STDs while on PrEP- Gonorrhea/chlamydia NAAT (crucial to screen from all applicable sites- oropharyngeal, rectal, urethral, cervicovaginal), syphilis. Consider HCV screening as well depending on risk factors.
    b. All women should have urine pregnancy test done at each follow up. Pregnancy is not a contraindication to PrEP but risks/benefits need to be discussed with patient and if pregnant the patient's OB should be aware that patient is on PrEP.
4. **Possible side effects of PrEP**
    a. Most common side effects of FTC/TDF include nausea, headache, fatigue, abdominal pain, diarrhea. Most of these symptoms are mild and resolve within first month. Strategies that can help include taking pill with food or at night before bedtime.
    b. It is possible to also see renal function decline and decrease in bone mineral density with TDF. Renal toxicity is more common in those with pre-existing renal disease. It is rare in PrEP patients (more common in HIV+ patients). CrCl <60 at baseline is contraindication for Truvada.

5. **What if patients forget a dose?**
    a. Forgetting a dose is common. PrEP has been shown to be effective with at least 4 doses/week, though we always encourage complete adherence.
    b. If patient forgets a dose, take it when they remember. It's OK if it is taken late. Resume

same schedule next day. Avoid double dosing- just resume regular schedule.

c. Strategies that can help- taking pill same time as something else routine (eating breakfast, brushing teeth, etc), setting alarms or phone reminders, using pill boxes, keeping one on patient (in purse/pocket, on keychain, in wallet).
d. If patient stops PrEP for more than 7 days, they need to be rescreened for HIV before restarting PrEP.

6. **When to discontinue PrEP?**
    a. If patient tests HIV-positive, discontinue immediately and refer these patients to PACE
    b. If renal disease develops
    c. If risk behaviors are reduced to the extent that PrEP is no longer needed or desired
    d. If patient requests to discontinue PrEP
    e. **Note:** Discontinuation of PrEP in patients with chronic active hepatitis B can cause exacerbations of hepatitis B and the patient's GI provider should be involved in decision to discontinue.

iv. **What if patients miss every 3 month visit with provider?**

1. **Do not** provide refills if patient misses follow up with you. It is important to stress with patients that adherence with visits are critical for remaining on PrEP. Patients need to be screened every 3 months to make sure they have not acquired HIV in the interim. If a patient misses their appointment, refills should not be provided and patient will need to be rescreened at time they are rescheduled prior to restarting PrEP.

3. Indications for referral

a. URGENT referral

i. **Patients who test positive for HIV should be immediately referred to PACE clinic**. Do not proceed with PrEP.

ii. Any patient who seroconverts (contracts HIV) while on PrEP should be immediately referred to PACE clinic to be seen and treated.

4. Please include the following with your referral

a. Results of any pre-referral testing

Summary PrEP Algorithm:

Pre-Prescription Visit:

Discuss PrEP use; clarify misconceptions

Perform following laboratory tests:

- HIV test
- Metabolic panel
- Urinalysis
- Hepatitis A, B, C serology
- STI screening
- Pregnancy test

After confirmation of negative HIV test: **Prescribe 30-day supply of PrEP.** Follow up in 2 weeks to assess side-effects (in person or by phone)

Adherence and **commitment** should be assessed at each visit. Schedule visits **every 30 days** for patients who report poor adherence or intermittent use.

30-Day Visit

Assess:

- Side-effects
- Serum creatinine and calculated creatinine clearance for patients with borderline renal function or an increased risk for kidney disease (>65 years of age, black race, hypertension, or diabetes)
- Discuss risk reduction and provide condoms

Prescribe 60-day refill; patient must come in for 3-month visit for HIV test and f/up, then 90-day schedule can begin

3-Month Visit

- HIV test
- Ask about STI symptoms
- Discuss risk reduction and provide condoms
- Serum creatinine and calculated creatinine clearance
- Pregnancy test

6-Month Visit

- HIV test
- Obtain STI screening tests
- Discuss risk reduction and provide condoms
- Pregnancy test

9-Month Visit

- HIV test
- Ask about STI symptoms
- Discuss risk reduction and provide condoms
- Serum creatinine and calculated creatinine clearance
- Pregnancy test

12-Month Visit

- HIV test
- Obtain STI screening tests
- HCV serology for MSM, IDUs, and those with multiple sexual partners
- Discuss risk reduction and provide condoms
- Urinalysis
- Pregnancy test

HIV POST-EXPOSURE PROPHYLAXIS:

Indications for PEP should be examined in both the non-occupational setting and occupational setting. With regards to the occupational setting these inquiries should be directed to Santa Clara Valley Medical Center Employee Health.

Inclusion criteria and recommendation for PEP:

- Adult patients seeking care within 72 hours following potential non-occupational exposure placing them at increased risk of HIV infection.
    - Bodily fluids from source patient are known to be HIV positive OR the status is unknown, but HIV positivity is suspected (MPC PREP MD or PACE MD on call via Amion must be consulted if status of source patient is unknown).

      AND
    - Higher risk exposures such as:
        - Receptive or insertive anal or vaginal intercourse without known barrier protection (condom) use.
        - Exposure to blood or other contagious fluids (semen, pre-ejaculate, vaginal fluid, breast milk, and saliva or vomit only if the latter two contain visible amounts of blood) via injury (i.e. syringe/needle sharing, human bites, needle sticks) or via contact with mucus membranes or open skin.

Exclusion criteria:

- Exposed patient is HIV positive
- Low risk exposures:
    - Receptive and insertive oral vaginal contact
    - Receptive and insertive oral anal contact
    - Receptive and insertive oral penile contact with or without ejaculation
- Other exposures that do not warrant PEP:
    - Oral to oral contact without mucosal damage (kissing, mouth to mouth resuscitation)
    - Human bites without blood
    - Exposure to solid bore syringes or sharps not in contact with recent blood
    - Mutual masturbation without skin breakdown or blood exposure

If PEP is determined to be indicated a prescription will be sent to Moorpark pharmacy as below and the patient will be advised to wait at PACE until the Rx is ready. Staff will coordinate with the pharmacy to ensure the patient does not leave the clinic until the prescription is ready for pickup with cost that is acceptable to the patient and ideally $0.00. When the source patient is known to be HIV+, HIV-1 RNA and historical genotype information should be reviewed to ensure that the PEP regimen selected will be anticipated to have adequate antiviral activity (at least 2-fully active drugs).

Initial Prescriptions: 1st trimester fetal exposure NOT anticipated

Truvada (tenofovir disoproxil fumarate/emtricitabine) 300/200 mg tablet
- *Sig*: Take 1 tablet by mouth once daily with or without food. FOR POST EXPOSURE PROPHYLAXIS.
- *Quantity*: 30 tablets
- *Refills*: Zero
- *Rx Comment*: ICD10 Z20.6 – Exposure to HIV. CONTACT PACE at 408 885 4690 if any billing issues.

PLUS

Tivicay (dolutegravir) 50 mg tablet
- *Sig*: Take 1 tablet by mouth once daily with or without food. FOR POST EXPOSURE PROPHYLAXIS.
- *Quantity*: 30 tablets
- *Refills*: Zero
- *Rx Comment*: ICD10 Z20.6 – Exposure to HIV. CONTACT PACE at 408 885 4690 if any billing issues.

Initial Prescriptions: 1st trimester fetal exposure anticipated

Truvada (tenofovir disoproxil fumarate/emtricitabine) 300/200 mg tablet
- *Sig*: Take 1 tablet by mouth once daily with or without food. FOR POST EXPOSURE PROPHYLAXIS.
- *Quantity*: 30 tablets
- *Refills*: Zero
- *Rx Comment*: ICD10 Z20.6 – Exposure to HIV. CONTACT PACE at 408 885 4690 if any billing issues.

PLUS

Isentress (raltegravir) 400 mg tablet
- *Sig*: Take 1 tablet by mouth TWICE daily with or without food. FOR POST EXPOSURE PROPHYLAXIS.
- *Quantity*: 60 tablets

- *Refills*: Zero
- *Rx Comment*: ICD10 Z20.6 – Exposure to HIV. CONTACT PACE at 408 885 4690 if any billing issues.

Deviation from the above regimens including 2-drug PEP may occur at the discretion of the MD to address concerns related to resistance, risk for toxicity, adherence, or cost/access.

The following monitoring schedule will be used after PEP initiation:

- One week after exposure
  - MPC PREP provider calls patient to assess adherence and tolerability
  - 4 to 6 weeks follow up appointment scheduled in clinic
- Two to three weeks after exposure
  - MPC PREP provider calls patient if not previously reached during 1-week phone call and/or if the patient needs additional monitoring/counseling
- Four to six weeks after exposure
  - HIV-1 and HIV-2 Antibodies, P24 Antigen
  - Syphilis Antibody EIA with Reflex to RPR Quant
  - Triple site screen for gonorrhea, chlamydia (rectal, throat, urethral)
  - Trichomonas vaginal swab (sexually active patients born female only) (self or clinician collected)
  - Creatinine
  - Liver Function Tests
  - Pregnancy, urine (patients of reproductive potential only)
- Three months after exposure
  - HIV-1 and HIV-2 Antibodies, P24 Antigen
- Six months after exposure
  - HIV-1 and HIV-2 Antibodies, P24 Antigen if patient was acutely infected with Hepatitis C from original exposure
  - Hepatitis B surface antigen, surface antibody, and core antibody if patient showed baseline susceptibility to hepatitis B

- Anti-HCV with reflex to HCV RNA Qt PCR if patient showed baseline susceptibility to hepatitis C
- Syphilis Antibody EIA with Reflex to RPR Quant – if positive, repeat serology 6 months post-treatment to document four-fold decline in RPR titer

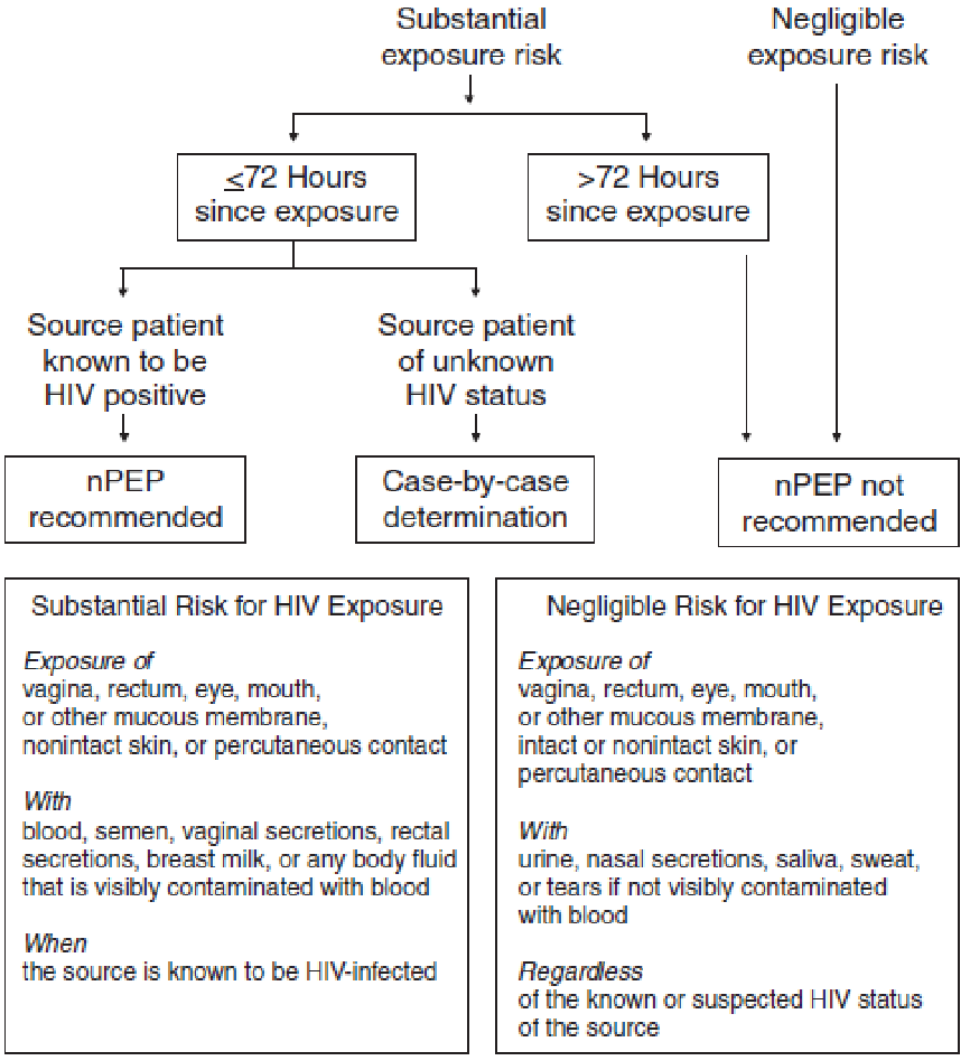
- Monitoring of patient status includes patient adherence with medication regimen, laboratory testing and follow-up with clinic visits or telephone contact. Failure to adhere to the requirements of this protocol (3 or more missed phone calls and/or any missed laboratory test) is considered a safety issue and may be detrimental to the patient's health. This will result in a notification by MPC PREP outreach to the patient's primary clinician and/or public health.

- The patient will be seen by an MPC PREP provider for the initial clinic visit, followed by telephone calls prior to the time when each laboratory investigation is due. Six months after exposure, the patient will no longer be contacted by the above parties unless further infectious disease issues arise or if transition to PrEP is made.

- The patient's PCP will be notified of enrollment into the PEP protocol. The PCP will receive regular communication from MPC PREP outreach or MPC PREP pharmacist if requested. The patient should be referred to their PCP for any ongoing medical issues unrelated to PEP therapy. If the patient elects out of the PEP protocol once enrolled, the PCP on record will be notified of the change in patient status.

1. PEP Algorithm:

FIGURE 1. Algorithm for evaluation and treatment of possible nonoccupational HIV exposures



Revisions:
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